BACKGROUND: As age increases, prevalence of type 2 diabetes in the U.S. rises dramatically as the population approaches and enters Medicare eligibility (CDC). Although ensuring category access, CMS formulary guidelines for Medicare Part D (MPD) coverage do not take into account the effects of cost-sharing burden on patient compliance. Literature demonstrates that patient adherence is reduced with higher copayment costs and consequently, the beneficial clinical impacts may likely be unrealized for many patients. **OBJECTIVES:** To investigate access to diabetic medications for MPD patients compared to commercially covered lives. Exploring copay differentials amongst these populations, insight is gained on how MPD differs from commercial access to diabetes medications. **METHODS:** Analysis of the Walters Kluwer Pharma Solutions Source Longitudinal Patient Database, sampling of 26.7 million commercial lives and 5 million Medicare Part D lives in 2009. Low Income Subsidy covered lives were excluded. **RESULTS:** Average drug copayment for metformin and sulfonylurea for commercial and MPD patients is $15 and $19 respectively. Average drug copayment for insulin glargine in commercial is $17 and $27 for MPD patients, for branded pioglitazone $31 and $52, and exenatide $32 and $68. **CONCLUSIONS:** Copayment differentials across these populations are small for generic therapies and grow larger for branded, novel diabetic agents. This data would suggest a broader, more inclusive review is needed to assess how the financial burden felt by MPD diabetes patients affects patient compliance and outcomes. Further investigation is needed to study the potential value that CMS would benefit from re-evaluating the cost sharing burden for this patient population.

PHP107

BIOMARKERS: A CHANGING PARADIGM FOR DEVELOPMENT

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The general perception is that pharma companies generally incorporate biomarker (BM) development into their processes when a drug response is not optimal following the results of phase 3 studies. Usually this is when poorer than expected efficacy results are achieved. In this scenario, the BM development enables targeting of a niche population that is representative of the responders, thus effectively increasing the efficacy making the product more attractive to payers and healthcare professionals. This late stage approach to BM development also fits with the commonly held belief that BMs are linked to reduced market access (MA), lower market shares and decreased product revenues. In such a situation BMs are often only developed retrospectively to overcome access issues. Our objective is to demonstrate that investment into BMs in the early phase of drug development (DD) is more commercially attractive. **METHODS:** Three scenarios of drug development were defined: 1) the current/traditional model, 2) where biomarker development is incorporated from phase I of development and 3) where biomarker development involves a concurrent Phase III investigation or Phase IV retrospective analysis. These scenarios were analyzed to determine the relationship between risk and reward using assumed cash-flow curves and net-present value analysis based upon those curves. In each case, the implications of integration of BM development at various stages and how this affects risk-reward were assessed. **RESULTS AND CONCLUSIONS:** The scenario analysis demonstrates that by shifting investment to earlier in the DD process, costs associated with investment-heavy Phase III will be reduced. Early incorporation of BMs into DD will improve the commercial and healthcare benefits and the drug will have the potential to benefit from shortened approval time, early MA and higher price.

PHP108

THE CASE OF RARE DISEASE DRUGS BEFORE AND AFTER THE INTRODUCTION OF PRICING BODIES: LESSONS LEARNED FROM BRAZIL AND CANADA, IMPLICATIONS FOR THE UNITED STATES

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OBJECTIVES: This poster examines the pharmaceutical price implication for rare disease products in two countries which recently developed technology assessment and pricing processes with a look toward the potential implications for the United States. **METHODS:** Case studies are built out of examining prices for the Multiple Sclerosis drugs interferon beta-1a and natalizumab in the context of Brazil, while the Gaucher's disease products imiglucerase and miglustat are studied in Canada. In each case, a brief overview of the health systems is given, with specific attention to the pricing bodies. The prices for drugs which came to market before and after the advent of a pricing body are compared relative to each other. These differences are then compared to the price differential in the US and UK to determine if the HTA body was instrumental in this pricing change. **RESULTS:** In Canada miglustat is 17.8% of the cost for imiglucerase while in the US it is 38%, with a similar trend in the price of MS drugs in Brazil. To some degree, the lower price is expected as the drug classes are different. However, the disparity between a 17.8% differential and a 38% differential suggests that the Canadian pricing body is used to apply downward pressure on the price of rare disease drugs. **CONCLUSIONS:** The price differential has distinct implications for the US market, in which payers may look towards developing a technology assessment process using cost effectiveness research to drive down costs due to the current environment. As one of the most important markets for pharmaceutical profits, this has considerable ramifications for industry in terms of income and innovation incentive.

PHP109

AN OUTCOMES PROFILE REGISTRY FOR ESTABLISHING A BASELINE MATRIX IN COMPARATIVE EFFECTIVENESS STUDIES IN PREDICTIVE PHARMACOLOGY

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We propose a novel applied decision analytics solution in clinical outcomes analysis for deriving outcomes to be used as benchmarks in designing appropriate therapies in personalized medicine and predictive pharmacology. The efficacy of comparative effectiveness research in clinical medicine and pharmacology is limited by the lack of a defined solution to derive clinical outcomes across diverse patient populations and a variety of disparate data sources that collectively define a clinical profile at particular point in time. An outcome at time T_1 is driven not only by static factors such as race, ethnicity and occupation, that are generally time-independent, but also by the condition profile and resultant outcome of the patient's condition at T_0. Our solution is an ensemble analytical framework that leverages a temporal rule induction algorithm to create derived outcomes profiles across the time continuum. It performs analysis on structured and unstructured data from EMR/EHR, clinical, biological, biomarker, behavioral and demographic data sources that are integrated into a composite data warehouse via our propriety semantic resolution and natural language processing algorithms. The outcomes profiles reflect an index or aggregate score for the amalgamation of all available data for a particular patient at a particular time. Outcomes profiles from thousands of samples are catalogued and normalized in a registry and are used to establish a baseline matrix for application in higher level statistical and predictive analyses for comparative effectiveness studies in pharmacology. Using this approach, it is possible to determine based on available data both the appropriate treatment to affect a desired outcome and the predicted outcome based on a given treatment at a given time.

PHP110

BIOSIMILARS LITERATURE REVIEW: THE CURRENT LANDSCAPE AND IMPLICATIONS OF RECENT HEALTH CARE LEGISLATION FOR THE UNITED STATES MARKET

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Biosimilars represent an emerging area of interest for the pharmaceutical industry. Biosimilars are essentially 'generic' versions of 'branded' biologics, but are not considered identical to the innovator biologic. In 2009, half of the top ten selling drugs were biologics; this proportion is expected to reach 80% by 2015. Biosimilars are seen as a cost-saving alternative to payers, and as generic drugs take over the market, manufacturers are depending on biologics to drive growth. However, they will need to consider the inherent challenges in this market. This literature review was undertaken to provide a summary of the current state of affairs with biosimilars, including a review of the recent healthcare legislation and policies in countries that already have formal guidance regarding biosimilars approval. Significant resources are required to participate in the biosimilars market, including regulatory expertise, manufacturing capabilities, and global market reach. One concern to potential market players is the uncertainty regarding the approval process for biosimilars in the United States (U.S.). The Patient Protection and Affordable Care Act (PPACA 2009) authorized the FDA to develop an abbreviated regulatory pathway for biosimilar approval but guidance has not yet been issued. It is important for the U.S. to learn from other countries. This review includes a summary of other countries' approaches to biosimilars approval. For example, since 2006, the European Medicines Agency has had extensive requirements for pre-clinical and clinical data to demonstrate quality, safety, and efficacy of the product seeking approval. Questions remain including: How will the competitive landscape look as biosimilars enter the market? What will be the comfort level with substitutability of biosimilars? Will there be patent protection for the manufacturing process? And, what will the FDA require in terms of clinical trials and other supportive data to recognize biosimilars? The literature review will address these questions and more.

PHP111

OVER INFLATION OF THE GENETIC CONTRIBUTION TO SCHIZOPHRENIA: IMPLICATIONS FOR NOVEL THERAPEUTICS

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The biological model of schizophrenia remains the dominant model within mental health services and has a powerful and enduring influence on the prevailing format of mental health care delivery to patients with the diagnosis. There exists almost universal acceptance of a genetic cause for schizophrenia though in many instances this conflicts both philosophically and clinically with a person-centred recovery orientated approach. A review of the underpinning research that supports the genetic argument was conducted. Appraisal of family, twin and adoption studies uncovers serious flaws in the methodologies and statistical analyses used in studies. These flaws tend to artificially inflate the perceived genetic contribution to schizophrenia and moreover may also invalidate many of the reported study findings. There exists an absence of a replicable and consistent finding indicating a clear genetic pathway to schizophrenia. Novel therapeutic approaches aimed at neurotransmitter receptor site abnormalities should not therefore be discouraged by any fundamental refocus on gene therapy approaches.

PHP112

DEFINITIONAL CRITERIA FOR CHRONIC FATIGUE SYNDROME: A CRITICAL REVIEW

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Chronic Fatigue Syndrome (CFS) is an enigmatic and misunderstood clinical entity. A broad range of etiological mechanisms have been suggested including endocrine, immune, infectious, muscular and neurological abnormalities. However, the cause remains elusive thus impacting on developing models of evidenced based thera-